

Application No. 09/869,282
Amendment dated October 21, 2010
Reply to Office Action of June 22, 2010

REMARKS

**Reconsideration And Allowance
Are Respectfully Requested.**

Claims 237-260 are currently pending. Claims 237, 238, 242, 243, 244, 249 and 250 have been amended. New claims 251-260 have been added. Claims 1-236 were previously canceled. No new matter has been added. Reconsideration is respectfully requested.

Claims 237 stands rejected under 35 U.S.C. § 112, second paragraph. This rejection is believed to be overcome by the preceding amendments. In particular, cannula has been removed from claim 237 and "suture-type material" has been changed to "suture material" in order to directly correspond with the language of the Specification (See Page 20, line 29, through Page 21, line 21). With regard to "formed from a unitary piece of metal", this language has been amended to make it clear that the marker is in the form of a unitary piece of metal. With regard to the language "multiple passes", no amendments have been made as the Specification on Page 21, lines 7-8 makes it perfectly clear what Applicants are referring to and one of ordinary skill in the art would understand a suture having multiple passes. With regard to claim 238, the language regarding a body is correct as contrary to the Examiner's understanding, a body has not been recited in claim 237.

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Claims 237-250 have also been rejected multiple times under obvious type double patenting in view of eight different pending applications and 3 issued patents all having common ownership to the present application. These rejections are deemed to be baseless. All of the applications and patents may be directed to markers or methods of inserting markers, but each application is directed to different and distinct features of the markers or methods. If in fact, as the Examiner suggests, they are all obvious variations of one another, then why have the 3 patents used in these double patenting rejections issued on what the Examiner considers to be the same invention?

With regard to the 35 U.S.C. § 103 rejections of claims 237-240, 241-246 and 248- 250 based upon U.S. Patent Application Publication No. 2002/05888 to Fulton in view the article to Robinson and claims 240 and 247 based upon Fulton in view of Robinson and U.S. Patent No. 5,702,449 to McKay, these rejections are traversed for the following reason.

Claim 237 specifically requires the marking device comprises a first component and a second component. The first component is a bioabsorbable suture material and the second component is a unitary piece of metal forming a marker. The second component is carried by the first component. Obviousness under 35 U.S.C. § 103 involves underlying factual considerations regarding (1) the scope and content of the prior art, (2) the differences between

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the prior art and the claimed invention, (3) the level of ordinary skill in the art, and (4) the relevant secondary considerations. Graham v. John Deere Co., 383 U.S. 1, 17-18 (1996). A claimed invention is invalid for obviousness “if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains”. 35 U.S.C. § 103. Obviousness being a question of law, this Court reviews it *de novo*. Cybor Corp. v. FAS Techs., Inc., 128 F.3d 1448, 1456 (Fed. Cir. 1998); KCJ Corp. v. Kinetic Concepts, Inc., 223 F.3d 1351, 1355 (Fed. Cir. 2000).

A *prima facie* rejection based upon obviousness requires that the prior art reference (or references when combined) must teach or suggest all of the claim limitations. In order to do this requires that the claims be construed in light of the specification as one of ordinary skill in the art would understand the terms used therein. Phillips v. AWH Corp., 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc).

The claimed structure is not disclosed by either Fulton or Robinson. Thus, regardless of how they are combined they would fail to teach the claimed invention. Nowhere in the disclosure of Fulton or Robinson is a suture material carrying a unitary metal piece disclosed. As such, each and every feature of the claimed invention is not disclosed as required by Phillips.

As noted by the Examiner, Fulton does not expressly teach the second material is metal, let alone a unitary piece of metal. Robinson does not compensate for the shortcomings of Fulton. Robinson teaches collagen plugs treated with tantalum microparticles used to mechanically plug the tract formed when performing a biopsy. The addition of microparticles to the preformed collagen network of Robinson is surely not the same as a unitary piece of metal as claimed by Applicants.

Claim 238 depends from claim 237 discussed above and further includes the limitation of the suture material having multiple passes forming a body. This is the same limitation found in independent claims 244 and 250. Further to the remarks set forth above with regard to claim 237, the Examiner fails to address the limitation of the first component including multiple passes of the suture material forming a body with the second component carried therein. Contrary to the Examiner's belief, the language "multiple passes" could easily and clearly be understood by one of ordinary skill in the art when read in light of Applicant's Specification and drawings. No such structure is taught by either Fulton or Robinson. This limitation cannot merely be dismissed by the Examiner and must be properly addressed by a rationale as to why it is obvious.

With regard to claims 240 and 247, while titanium may be taught to be a known biocompatible material by McKay, this alone is not a sufficient rationale to modify the combination of Fulton and Robinson. McKay is concerned with a spinal implant to be

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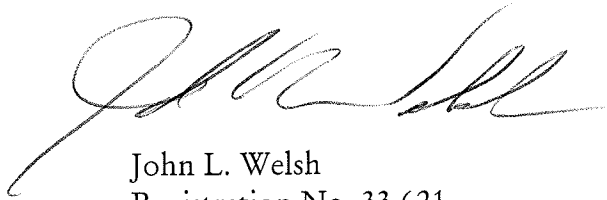
engaged between adjacent vertebrae and the second component of metal is a sleeve 15 to withstand compressive force and has nothing to do with marking. Quite simply, McKay's sleeve has nothing to do with marking nor is in the same field as the marking devices disclosed by Fulton and one of ordinary skill in the art would not be looking to or combining elements from a spinal implant into a biopsy marking device.

With regard to the remaining dependent claims, the Office Action fails to properly address the recited limitations. In claims 239 and 246, the first component has been claimed to be flexible and the Office Action fails to address this limitation. In claims 241 and 248, the second component has been claimed to be formed in a shape other than a sphere and the Office Action fails to address this limitation. In claims 242 and 249, the suture material of the first component is claimed to be bent and the Office Action fails to address this limitation. Lastly, claim 243 sets forth the lumen of the elongated member includes internal walls and the first component is resilient and in contact with the internal walls when preloaded within the elongate member and the Office Action fails to address this limitation.

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It is believed that this case is in condition for allowance and reconsideration thereof and early issuance is respectfully requested. If it is felt that an interview would expedite prosecution of this application, please do not hesitate to contact applicants' representative at the below number.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'John L. Welsh', is positioned above the printed name and registration number.

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